

### REMARKS

Applicant thanks the Examiner for withdrawing both the restriction requirement and the species election, and for confirming that all claims are currently pending.

Applicant also notes that the Examiner then granted priority only to application Ser. No. 09/597,206 (now U.S. Patent No. 6,602,522) with a filing date of June 20, 2000.

The Examiner then requested Applicant's cooperation in correcting any errors in the specification of which Applicant becomes aware. Applicant will of course cooperate and bring to the Examiner's attention any errors of which Applicant becomes aware.

The Applicant also notes that it will respect the nature of any trademark used in this application and will take every reasonable effort to prevent the use of any trademarks in a manner that might adversely affect the validity of said trademarks.

The Examiner then rejected Claim 9 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In response, Applicant has canceled Claim. Therefore, Applicant respectfully requests removal of this now-moot rejection.

The Examiner next rejected Claims 1-3, 6, 7 and 20-22 under 35 U.S.C. 102(b) as being anticipated by Morella et al. (WO 94/05262). In response, Applicant has amended independent Claims 1, 20 and 21 to recite that the active ingredient can be only anti-diabetics, HMG-CoA reductase inhibitors or mixtures thereof. This does not represent new matter, and support can be found at, *inter alia*, page 7, line 18 and page 8, lines 21-22 of the specification as originally filed. Additionally, Claim 3 has been canceled. Neither of the two active ingredients listed in Claims 1, 20 and 21 are taught by Morella. Therefore, Applicant respectfully requests removal of this ground of rejection.

The Examiner then rejected Claims 8-9 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. In response, Applicant has canceled Claims 8-9. Therefore, Applicant respectfully requests removal of this ground of rejection as rendered moot due to cancellation of the claims.

The Examiner next rejected Claims 11-14 and 17-19 under 35 U.S.C. 103(a) as being unpatentable over Morella in view of Kanios et al. (U.S. Patent No. 5,719,197). In response, Applicant has canceled Claims 11-14 and 17-19. Applicant respectfully

requests removal of this ground of rejection as rendered moot due to cancellation of the claims.

The Examiner then rejected Claims 4 and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. in view of Curatolo et al. (U.S. Pat. No. 6,068,850). In response, Applicant has canceled Claims 4 and 8-10. Therefore, Applicant respectfully requests removal of this ground of rejection as rendered moot due to cancellation of the claims.

The Examiner then rejected Claims 4-5, 11-13, 15, 16 and 18-19 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. in view of Acharya (U.S. Pat. No. 5,686,094). In response, Applicant has canceled Claims 4-5, 11-13, 15-16 and 18-19. Therefore, Applicant respectfully requests removal of this ground of rejection as rendered moot due to cancellation of the claims.

The Examiner then rejected Claims 1-2, 4, 7 and 10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Pat. No. 6,174,548 in view of Morella. In response, Applicant has canceled Claims 4 and 10 and amended Claim 1 to recite that the active ingredient can be only anti-diabetics, HMG-CoA reductase inhibitors or mixtures thereof. This does not represent new matter, and support can be found at, *inter alia*, page 7, line 18 and page 8, lines 21-22 of the specification as originally filed. Neither Morella nor the '548 patent teach, disclose, or suggest the use of anti-diabetics or HMG-CoA reductase inhibitors (or mixtures thereof), therefore it would not be obvious to one of ordinary skill in the art to combine the two references to create that which Applicant claims as the invention. Furthermore, even if it were obvious to combine the two references (which Applicant does not concede), that which Applicant claims as the invention would still not be created because, even by combining the two references, one skilled in the art would not create a composition with an anti-diabetic or HMG-CoA reductase inhibitor (or mixtures thereof). Therefore, Applicant respectfully requests removal of this ground of rejection.

The Examiner then rejected Claims 1, 4-10, 21 and 22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 5-11, 16 and 18-19 of U.S. Pat. No. 6,602,522. In response, Applicant has canceled Claims 4-5 and 8-10 and amended Claims 1 and 21 to recite that the active ingredient can

be only anti-diabetics, HMG-CoA reductase inhibitors or mixtures thereof. The '522 patent does not teach, disclose, or suggest the use of anti-diabetics or HMG-CoA reductase inhibitors (or mixtures thereof), therefore it would not be obvious to one of ordinary skill in the modify the reference to create that which Applicant claims as the invention. Furthermore, even if it were obvious to modify the reference (which Applicant does not concede), that which Applicant claims as the invention would still not be created because, even by modifying the reference, one skilled in the art would not be motivated to create a composition with an anti-diabetic or HMG-CoA reductase inhibitor (or mixtures thereof). Therefore, Applicant respectfully requests removal of this ground of rejection.

The Examiner then rejected Claims 1-3, 5-11, and 13-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Pat. No.6,733,778 in view of Morella. In response, Applicant has canceled Claims 3, 5, 8-11, and 13-16 and amended Claim 1 to recite that the active ingredient can be only anti-diabetics, HMG-CoA reductase inhibitors or mixtures thereof. This does not represent new matter, and support can be found at, *inter alia*, page 7, line 18 and page 8, lines 21-22 of the specification as originally filed. Neither Morella nor the '778 patent teach, disclose, or suggest the use of anti-diabetics or HMG-CoA reductase inhibitors (or mixtures thereof), therefore it would not be obvious to one of ordinary skill in the art to combine the two references to create that which Applicant claims as the invention. Furthermore, even if it were obvious to combine the two references (which Applicant does not concede), that which Applicant claims as the invention would still not be created because, even by combining the two references, one skilled in the art would not create a composition with an anti-diabetic or HMG-CoA reductase inhibitor. Therefore, Applicant respectfully requests removal of this ground of rejection.

Applicant believes that these arguments and amendments preclude the need for terminal disclaimers. However, Applicant is prepared to file terminal disclaimers in the event that the arguments and amendments are not persuasive.

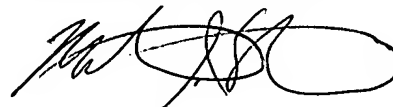
The Examiner then noted that there is almost an entire page break between the text on the top of page 3 of the specification and the text on page 4. The Examiner is authorized to remove the page break under 37 CFR 1.121(b)(1)(i) and/or MPEP

§1302.04(G). The Examiner also requested that a space be inserted between the number 80 and wt%. Applicant presumes that the Examiner was referring to Claim 9 as originally filed. If Applicant's presumption is correct, then the Examiner's suggestion is rendered moot as Applicant has canceled Claim 9 in this Amendment. However, if Applicant's presumption is incorrect, the Examiner is authorized under MPEP §1302.04(F) and/or (G) to insert a space between the number 80 and wt%.

Applicant also added new claims 23-37. These new claims do not represent new matter. Support for Claims 22-28 can be found at, *inter alia*, page 8, line 20 and page 21, line 6 (i.e., Example 7) of the specification as originally filed. Support for Claims 29-31 can be found at, *inter alia*, page 22, line 11 (i.e., Example 8) of the specification as originally filed. Support for Claims 32, 34 and 36 can be found at, *inter alia*, page 10, lines 7-9 of the specification as originally filed. Support for Claims 33, 35 and 37 can be found at, *inter alia*, page 7, line 14 of the specification as originally filed. Applicant does not believe any fee is required for the addition of these new claims as the total number of claims remains at 22. Notwithstanding, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540 for any fee required. A duplicate copy of this sheet is enclosed.

Based on the above, Applicant respectfully submits that the claims of the present invention are in proper form for allowance. Favorable consideration and early allowance are therefore respectfully requested and earnestly solicited.

Respectfully submitted,

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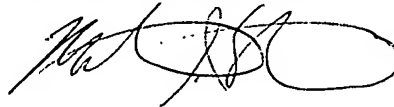
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